December 11, 2019

FUJIFILM Corporation
% Jeffrey Wan
Senior Regulatory Affairs Specialist
FUJIFILM Medical Systems U.S.A, Inc.
81 Hartwell Avenue, Suite 300
Lexington, MA 02421

Re: K193123
Trade/Device Name: FUJIFILM Distal Cap Models 33-40
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDS, FDF
Dated: November 8, 2019
Received: November 12, 2019

Dear Jeffrey Wan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen, PhD
Acting Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193123

Device Name

FUJIFILM Distal Cap Models 33-40

Indications for Use *(Describe)*

Distal Cap Models DH-33GR, DH-34CR, and DH-40GR are intended to be used in combination with compatible endoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.

Distal Cap Models DH-35GZ, DH-37CZ, DH-38CZ, and DH-39CZ are intended to be used in combination with compatible endoscopes to maintain the field of view during observation of the digestive tract.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
FUJIFILM Distal Cap Models 33-40

Date: November 8, 2019

Submitter's Information:

FUJIFILM Corporation
798 Miyanodai Kaisei-Machi
Ashigarakami-Gun, Kanagawa, 258-8538, Japan
FDA Establishment Registration Number: 3001722928

Contact Person:

Jeffrey Wan
Senior Regulatory Affairs Specialist
Telephone: (201) 675-8947
E-Mail: jeffrey.wan@fujifilm.com

Identification of the Proposed Device:

Proprietary/Trade Name:	FUJIFILM Distal Cap Models 33-40
Common Name:	Endoscopic Accessory
Device Class:	Class II
Review Panel:	Gastroenterology/Urology
Classification:	Endoscope and accessories, 21 C.F.R. § 876.1500
Product Codes:	FDS, FDF

Predicate Device:

FUJIFILM Hood Models DH-28GR, DH-29CR, DH-30CR (K162749)

Intended Use / Indications for Use:

Distal Cap Models DH-33GR, DH-34CR, and DH-40GR are intended to be used in combination with compatible endoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.

Distal Cap Models DH-35GZ, DH-37CZ, DH-38CZ, and DH-39CZ are intended to be used in combination with compatible endoscopes to maintain the field of view during observation of the digestive tract.

Device Description:

FUJIFILM Distal Cap Models 33-40 are comprised of an attaching portion and a distal portion. DH-33GR, DH-34CR, DH-35GZ, and DH-40GR feature drain slits, which prevent fluids from lodging on

the surface of the endoscope. DH-33GR and DH-34CR also feature guide grooves to facilitate the use of endotherapy devices.

Technological Characteristics:

FUJIFILM Distal Cap Models 33-40 differ from the predicate devices DH-28GR, DH-29CR, and DH-30CR in terms of technological characteristics. The subject and predicate devices share the same mode of operation and intended use.

A summary of major differences between the subject and predicate devices is provided as follows:

- Compatibility with applicable endoscopes
- Dimensional changes
- Introduction of guide grooves for DH-33GR and DH-34CR
- Expansion of storage and transportation conditions to a temperature range of -20°C to 60°C and a humidity range of 10 to 95% RH.
- Material changes

Performance Data:

Sterility of the subject devices was evaluated using the following consensus standards: ISO 11135:2014 and ASTM F1980-16.

Biocompatibility of the subject devices was evaluated using the following consensus standards: ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-7:2008, and ISO 10993-10. Biocompatibility testing was performed in accordance with the FDA guidance—Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"—published June 16, 2016.

Storage and transportation testing was conducted on the subject devices to validate the expanded temperature and humidity ranges.

Bench testing was conducted to demonstrate that the subject devices are attached securely such that they will not detach during use.

Additional performance specifications were evaluated against pre-defined acceptance criteria.

Substantial Equivalence:

The subject devices FUJIFILM Distal Cap Models 33-40 are substantially equivalent to the predicate devices, FUJIFILM Hood Models DH-28GR, DH-29CR, and DH-30CR (K162749). The subject and predicate devices share the same intended use. Bench testing demonstrates that the differences in technological characteristics raise no new issues of safety or effectiveness. The change in materials was validated via biocompatibility testing. Thus, the subject devices are substantially equivalent to the predicate devices.

Conclusions:

The subject devices FUJIFILM Distal Cap Models 33-40 are substantially equivalent to the predicate devices based on the same intended use and similar indications for use, technological characteristics, and materials.